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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,053	07/24/2003	Claus Yding Andersen	6203.214-US	1429
Reza Green Novo Nordisk Pharmaceuticals, Inc. 100 College Road West Princeton, NJ 08540				
EXAMINER SAUCIER, SANDRA E				
ART UNIT		PAPER NUMBER		
1651				
MAIL DATE		DELIVERY MODE		
11/25/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/626,053

**Applicant(s)**

ANDERSEN ET AL.

**Examiner**

Sandra Saucier

**Art Unit**

1651

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 44-62 is/are pending in the application.
- 4a) Of the above claim(s) 51-55, 57, 58, 60 and 62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 44-50, 56, 59 and 61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
- Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

Claims 44–62 are pending. Claims 44–50, 56, 59, 61 are under examination. Claims 51–55, 57, 58, 60, 62 have been withdrawn.

***Election/Restriction***

Applicants elected species of FF-MAS for examination 7/10/06.

Applicants elected Group II, directed to the use of growth factor in a process of *in vitro* fertilization on 1/22/08.

This application contains claims drawn to an invention nonelected with traverse in the reply filed on 1/22/08. **A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.**

***Claim Rejections – 35 USC § 112***

**INDEFINITE**

Claims 44–50, 56, 59, 61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The last line of claim 44 now recites “and/or pre-embryos are formed and are cumulus enclosed oocytes.”. Are applicants now stating that zygotes are cumulus enclosed oocytes? This is clearly not so and leads to confusion over what is meant. Please do not stray from the specification for support for recitations.

***Claim Rejections – 35 USC § 102***

Claims 44–47, 50, 56, 61 remain/are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Park *et al.* [U].

The claims are directed to a method for *in vitro* fertilization comprising: recovering an oocyte from a female subject,

culturing oocytes and sperm in a culture medium containing an additive capable of endogenous stimulation of the accumulation of a meiosis activating sterol (elected species of growth factor),

allowing the oocyte to progress to metaphase II, wherein the culturing step lasts until zygotes and/or pre-embryos are formed.

Park *et al.* disclose an *in vitro* method of culturing and maturing oocytes in a culture medium which contains EGF and sperm and allowing the zygotes to develop, page 476, Experiment 1.

Claims 44–50, 61 remain/are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Illera *et al.* [V].

Illera *et al.* demonstrate maturation and culturing of oocytes in a medium which contains EGF, FSH and sperm and allowing zygotes to develop.

### ***Response to Arguments***

Applicant's arguments filed 9/11/08 have been fully considered but they are not persuasive.

Applicants argue that Park *et al.* do not disclose data supporting the effect of EGF on oocyte maturation. It is of no consequence whether or not Parks *et al.* disclose the same results as the instant specification because 1) the active steps are the same as claimed and 2) the ingredients of the medium are the same as claimed. Thus, one would reasonably expect the results of the method disclosed by Parks *et al.* and the instantly claimed method to be the same. If the results of Park *et al.* are different from the results of the examples in the instant specification, then that may be a consequence of other elements which are not present in the claimed method which are disclosed in the examples.

Applicants argue that Illera *et al.* use fetal calf serum which can interfere with results, and that Illera *et al.* show a decrease in fertilization rate when both EFG and IGF-1 are present. Please note that the instantly claimed method is open to the use of fetal calf serum and IGF-1 in the medium. Thus the instant claims read upon the method of Illera *et al.*. If the result of the instant examples is different from the results of Illera *et al.*, it may be that the conditions of the instant experiments are different from the conditions of Illera *et al.*; however, the claimed method does not reflect these differences and are still rejectable over the reference.

Please be careful not to enter new matter into the claims when amending.

***Claim Rejections – 35 USC § 103***

Claims 44-47, 50, 56, 59, 61 remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Yosef *et al.* [W].

The claims have been discussed above.

Ben-Yosef *et al.* disclose a method of *in vitro* fertilization comprising induction of ovulation (maturation) *in vivo* by injection of the intact animal with PMSG and hCG, harvesting the oocytes, incubating the oocytes with EGF, transferring the oocytes to a sperm suspension for fertilization (Materials and methods, page 136).

The reference lacks the continuous exposure of the oocytes to EGF during fertilization and zygote development.

In the absence of evidence of criticality, one of ordinary skill in the art may mature the oocyte in a medium containing a compound which assists maturation before transferring into a medium which does not contain such a compound for fertilization and zygote development.

Concentrations of compounds are *prima facie* obvious in the absence of criticality, See MPEP 2144.05II.

Claims 44–50, 56, 59, 61 remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over Illera *et al.* [V].

The claims have been discussed above.

Although Illera *et al.* matures the oocytes *in vitro* instead of *in vivo*, the oocytes will enter MII prior to fertilization. Thus, under this interpretation, all of the limitations of the claimed method are present in the method of the reference. One of skill in the art may mature the oocytes *in vitro* or *in vivo* to cause them to enter MII prior to fertilization in the absence of evidence to the contrary. Variation in the concentration of compounds is *prima facie* obvious, see MPEP 2144.05 I. and II. Also, in the absence of evidence of variation in mammals with regard to the response to growth factors and hormones, use of the same hormone/growth factors with mouse, bovine, porcine or human oocyte maturation and fertilization protocol would be obvious.

One of ordinary skill in the art would have been motivated at the time of invention to make this addition in order to obtain the results as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

### ***Response to Arguments***

Applicant's arguments filed 9/11/08 have been fully considered but they are not persuasive.

Applicants argue that Ben-Yosef *et al.* uses intact follicles from rats and in contrast, the present invention uses isolated oocyte–cumulus complexes.

However, this argument is not present in the claimed invention and is therefore unpersuasive.

Applicant argues that Illera *et al.* find a decrease in the fertilization rate when both EGF and IGF-1 are in the incubation medium. Please note that the instantly claimed method is open to the use of IGF-1 in the medium. Thus the instant claims read upon the method of Illera *et al.*. If the result of the instant examples is different from the results of Illera *et al.*, it may be that the conditions of the instant experiments are different from the conditions of Illera *et al.*; however, the claimed method does not reflect these differences and are still rejectable over the reference.

### ***Conclusion***

Applicant's amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Sandra Saucier/  
Primary Examiner, Art Unit 1651